ANNALS OF SURGERY
Vol. 237, No. 3, 358–362

Does Using a Laparoscopic Approach to Cholecystectomy Decrease the Risk of Surgical Site Infection?

Chesley Richards, MD, MPH, Jonathan Edwards, MS, David Culver, PhD, T. Grace Emori, RN, MS, James Tolson, BS, Robert Gaynes, MD, and the National Nosocomial Infections Surveillance (NNIS) System, Centers for Disease Control and Prevention

From the Centers for Disease Control and Prevention, Atlanta, Georgia

Objective
To assess the impact of laparoscopy on surgical site infections (SSIs) following cholecystectomy in a large population of patients

Summary Background Data
Previous investigations have demonstrated that laparoscopic cholecystectomy is associated with a shorter postoperative stay and fewer overall complications. Less is known about the impact of laparoscopy on the risk for SSIs.

Methods
Epidemiologic analysis was performed on data collected during a 7-year period (1992–1999) by participating hospitals in the National Nosocomial Infections Surveillance (NNIS) System in the United States.

Results
For 54,504 inpatient cholecystectomy procedures reported, use of the laparoscopic technique increased from 59% in 1992 to 79% in 1999. The overall rate of SSI was significantly lower for laparoscopic cholecystectomy than for open cholecystectomy. Overall, infecting organisms were similar for both approaches. Even after controlling for other significant factors, the risk for SSI was lower in patients undergoing the laparoscopic technique than the open technique.

Conclusions
Laparoscopic cholecystectomy is associated with a lower risk for SSI than open cholecystectomy, even after adjusting for other risk factors. For interhospital comparisons, SSI rates following cholecystectomy should be stratified by the type of technique.

Laparoscopic cholecystectomy, introduced in the late 1980s, has replaced the open technique for the majority of the 770,000 cholecystectomy procedures performed in the United States each year.[1] Although laparoscopic cholecystectomy is less invasive, requires shorter hospitalizations, and is associated with faster recovery than open cholecystectomy, little is known about the impact of laparoscopy on the risk for surgical site infections (SSIs). To assess the impact of laparoscopy on SSIs, we analyzed data from the National Nosocomial Infections Surveillance (NNIS) system to describe the characteristics of SSIs for both techniques and to assess SSI risk following laparoscopic cholecystectomy compared to open cholecystectomy.

METHODS

Data Source, Definitions, and Surveillance Methods

Data were collected on patients who underwent cholecystectomy from 1992 to 1999 in hospitals using surveillance definitions and protocols of the Centers for Disease Control and Prevention's NNIS system, which have been previously described.[2–4] Cholecystectomy included procedures identified by the *International Classification of Diseases, Ninth Revision* (ICD-9) codes 51.03, 51.04, or 51.2 to

Presented in part at the Fourth Decennial International Conference on Nosocomial and Healthcare-Associated Infections, Atlanta, Georgia, March 7, 2000.
Correspondence: Chesley Richards, MD, Centers for Disease Control and Prevention, Mailstop E-55, 1600 Clifton Road, Atlanta, GA 30333.
E-mail: cir6@cdc.gov
Accepted for publication July 2, 2002.

Table 1. DEFINITIONS OF SURGICAL SITE INFECTIONS, NNIS SYSTEM

Superficial surgical site infection
- Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision *and* patient has at least one of the following:
  - Purulent drainage from the superficial incision
  - Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
  - At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness or heat *and* the superficial incision is deliberately opened by surgeon unless incision is culture-negative
  - Diagnosis of superficial incisional SSI by the surgeon or attending physician

Deep surgical site infection
- Infection occurs within 30 days after the operative procedure *and* involves deep soft tissues (e.g., fascia and muscle layers) of the incision *and* the patient has at least one of the following:
  - Purulent drainage from the deep incision but not from the organ/space component of the surgical site
  - A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has *at least one* of the following signs or symptoms: fever (>38), or localized pain or tenderness, unless incision is culture-negative
  - An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
  - Diagnosis of a deep incisional SSI by a surgeon or attending physician

Organ/Space surgical site infection
- Infection occurs within 30 days after the operative procedure *and* the infection appears to be related to the operative procedure
- *And*, infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure
- *And* at least one of the following
  - Purulent drainage from a drain that is placed through a stab wound into the organ/space
  - Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
  - An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
  - Diagnosis of an organ/space SSI by a surgeon or attending physician

Horan TC, Gaynes RP, Martone WJ, et al. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol 1992; 13:606–608.

51.24. During a surveillance month in a participating hospital, all patients undergoing cholecystectomy were monitored, at least until hospital discharge, for SSI using standard NNIS definitions.[5,6] SSI definitions used in the NNIS system are given in Table 1. SSI rates were calculated by dividing the total number of SSIs by the total number of patients undergoing cholecystectomy.[4] Potential risk factors evaluated in univariate analysis included patient characteristics (age, gender, American Society of Anesthesiologists [ASA] preoperative risk score[7]), operation timing (duration of procedure, emergency procedures), and operation characteristics (surgical wound class, multiple procedures through same incision, procedure trauma related, use of general anesthesia).

Table 2. CHARACTERISTICS FOR OPEN AND LAPAROSCOPIC CHOLECYSTECTOMY

Characteristic	Open (n = 18,079)	Laparoscopic (n = 36,425)	*P* Value
Gender, % male	35	25	<.001
Age, years (median)	57	49	<.001
Age ≥ 60, %	47	32	<.001
ASA score ≥ 3, %	42	26	<.001
Operation duration, min (median)	87	65	<.0001
Duration ≥ 2 hours, %	30	12	<.001
Dirty/contaminated wound, %	9	6	<.001
Emergency procedures, %	16	9	<.001
Multiple procedures, same incision, %	19	6	<.001

Statistical Analysis

Risk factors for surgical site infection were initially assessed in univariate analysis using the chi-square test (categorical variables) and the Kruskal-Wallis test (continuous variables). To identify independent risk factors, logistic regression (SAS version 6.12) with stepwise elimination was used. A multivariate analysis was conducted to determine the independent risk factors using logistic regression with stepwise elimination. Variables found to be associated with risk for SSI in univariate analysis ($P < .20$) were included in the initial logistic regression model. Statistical significance was set at the 0.05 level.

RESULTS

Cholecystectomy Techniques

Between January 1992 and October 1999, NNIS hospitals reported data on 54,504 inpatient cholecystectomy procedures. The percentage of cholecystectomy procedures performed using the laparoscopic technique increased from 59% in 1992 to 79% in 1999 ($P < .001$). Compared to open procedures, patients undergoing the laparoscopic technique were younger, less likely to be male, and less likely to have ASA scores of 3 or more, dirty or contaminated wounds, emergency procedures, or multiple procedures through the same incision (Table 2). Virtually all patients underwent general anesthesia and almost no patients had trauma or implants. Laparoscopic procedures were shorter in duration than open procedures.

Table 3. PRIMARY PATHOGENS ASSOCIATED WITH SURGICAL SITE INFECTIONS (SSI) FOLLOWING CHOLECYSTECTOMY

Pathogen	Open (n = 226) n (%)	Laparoscopic (n = 116) n (%)
Gram-negative bacteria		
Enterobacter spp	25 (11)	15 (13)
Escherichia coli	37 (16)	17 (15)
Klebsiella pneumoniae	15 (7)	8 (7)
Other gram-negative organisms	25 (11)	18 (16)
Gram-positive bacteria		
Staphylococcus aureus	35 (16)	21 (18)
Coagulase-negative *Staphylococcus*	25 (11)	7 (6)
Enterococcus spp	32 (14)	11 (9)
Other gram-positive organisms	22 (10)	13 (11)
Fungi	10 (4)	6 (5)

SSIs

Overall, 554 (1%) SSIs were reported during the study period. The most common primary pathogens associated with surgical site infections were similar for both the open and laparoscopic techniques (Table 3). The majority of surgical site infections were due to gram positive bacteria. For both the laparoscopic and open techniques, SSIs were most likely to occur at superficial sites (Table 4). Although the percentage of organ/space infections following laparoscopy was higher than following the open technique (48% vs. 36%, $P = .006$), the site-specific SSI rate was substantially lower with laparoscopy than with the open technique. Most SSIs following the open technique were detected during the patient's hospital admission (69%), while most SSIs following laparoscopic technique were detected during postdischarge follow-up (38%) or on readmission (29%) (see Table 4).

SSI Rates by Potential Risk Factor

In univariate analysis, the overall risk of SSI was significantly lower for laparoscopic cholecystectomy than for open cholecystectomy (0.62% vs. 1.82%, relative risk = 0.3, $P = .001$). In addition, SSI rates were higher in patients with an ASA score of 3 or more, with a contaminated or dirty wound, following emergency procedures, when multiple procedures were performed through the same incision, in males, and in patients age 60 years or more ($P < .001$ in all analyses).

SSI rates decreased for both techniques until 1995. When stratified by type of operative technique, SSI rates following the laparoscopic technique were consistently lower than the open technique (Fig. 1).

Multivariate Risk Factor Analysis

Several risk factors identified in univariate analysis remained independently associated with SSI risk in multivariate analysis: laparoscope use, year, operation duration, age 60 or older, emergency procedure, male gender, contaminated or dirty wounds, ASA score of 3 or more, and multiple procedures through the same incision. The duration of surgery variable was used in the model as a continuous variable and was significantly associated with a small, linear increase in SSI risk. In addition, the risk of SSI was lower from 1995 to 1999 compared to years before 1995. In the full, adjusted logistic regression model that simultaneously controlled for these other significant factors, the risk for SSI remained significantly lower in patients undergoing the laparoscopic technique than the open technique (odds ratio = 0.61, 95% confidence interval 0.51–0.74) (Table 5).

DISCUSSION

The results of this analysis of data from a national, voluntary reporting system for nosocomial infections strongly suggest

Table 4. PERIOD OF DETECTION AND SSI SITE FOLLOWING CHOLECYSTECTOMY

	Open (n = 18,079)		Laparoscopic (n = 36,425)		
	n (%)	SSIs per 100 operations	n (%)	SSIs per 100 operations	*P* Value
SSI, period of detection*					
During hospitalization	158 (69)	0.87	55 (33)	0.15	<.001
Readmission	20 (9)	0.11	49 (29)	0.13	
Postdischarge	51 (22)	0.28	63 (38)	0.17	
SSI site†					
Superficial	152 (48)	0.84	96 (43)	0.26	<.001
Deep incisional	53 (17)	0.29	21 (9)	0.06	
Organ space	114 (35)	0.63	106 (48)	0.29	

* Total n = 396.
† Total n = 542.

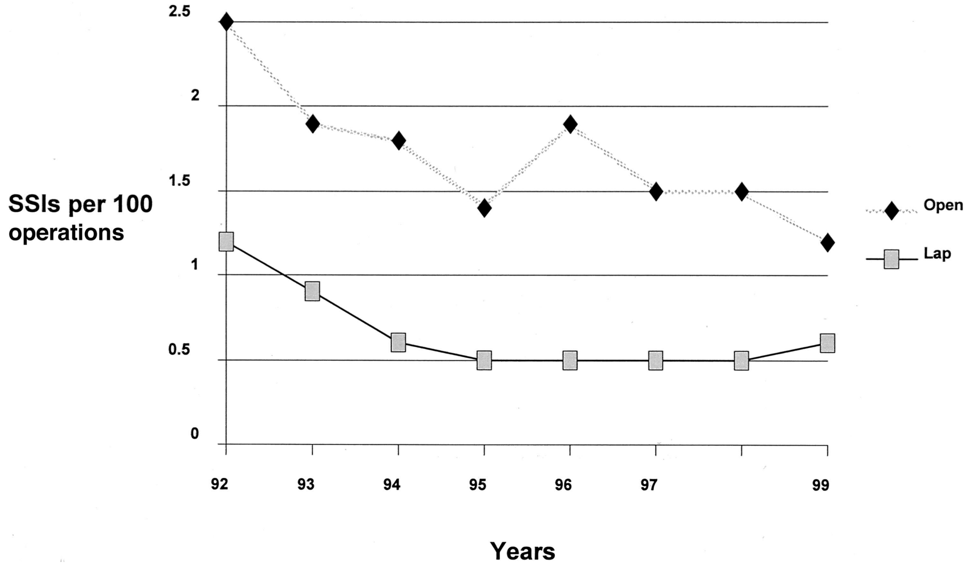

Figure 1. SSI rate after cholecystectomy by approach and year, NNIS system, 1992–1999.

that laparoscopic cholecystectomy is associated with a lower risk for SSI than open cholecystectomy, even after adjusting for other risk factors. No substantial differences in pathogen distribution from SSIs were seen for the two techniques. Although a higher proportion of SSIs were organ space infections for the laparoscopic technique, the total number of infections was fewer for laparoscopy and the site-specific rate of infection was substantially lower than open cholecystectomy.

These results add to and are consistent with a growing body of literature demonstrating the benefits of surgery using laparoscopy.[8–12] Previous studies have demonstrated that laparoscopic surgery results in fewer overall complications, shorter hospital stays, and shorter recovery time. In addition, laparoscopic procedures may have less impact on immune function than the open technique.[13] Our study identified a number of other risk factors for SSI following cholecystectomy procedures: older age, contaminated or dirty wound class, high ASA score, emergent procedures, and prolonged duration of surgery have been previously described. Performing multiple surgical procedures through the same incision as a cholecystectomy nearly doubled the risk of SSI independent of other factors. Additional procedures should be performed with care based on our analysis. Finally, our data suggested that male gender carried a slight increase in SSI risk. This finding remains unexplained, and previous studies have inconsistently reported gender as risk factor. Females have been reported to be at increased risk for SSI following coronary artery bypass graft surgery and for mortality from sepsis following surgery.[14,15] In contrast, males are at increased risk of postoperative SSI following colorectal surgery.[16]

There are three important implications of this study. First, laparoscopy is associated with a lower risk of SSI and should be used when patients are candidates for the technique. Second, SSI rates, stratified by the type of technique, should be used for interhospital comparisons. Infection rates reported by the NNIS system are stratified by the modified SSI risk index that includes factors for surgical wound class, ASA score, and operation duration.[3] In 1998, a fourth factor, operative technique, was added to the index for the cholecystectomy procedure.[17] The third implication is that simple risk stratification to predict risk for surgical site infections is less than optimal for interhospital comparisons. However, the large number of risk factors identified in this analysis is not amenable to a simple risk stratification scheme. Interhospital comparisons can be improved by using risk prediction models to calculate a standardized infection ratio in which an expected number of SSIs is calculated using the model and compared to the observed number of SSIs.[18] Statistical comparisons can be accomplished, where valid, through the calculation of a Z score. This method of

Table 5. INDEPENDENT RISK FACTORS FOR SSI FOLLOWING CHOLECYSTECTOMY: RESULTS OF LOGISTIC REGRESSION ANALYSIS

Risk Factor	Parameter Estimate	Odds Ratio	95% CI	*P* Value
Laparoscopy	−0.4908	0.61	0.51–0.74	<.001
Year, 1995 or later	−0.0918	0.91	0.88–0.95	<.001
Duration, minutes	0.00443	1.004	1.003–1.006	<.001
Age ≥ 60	0.2592	1.30	1.08–1.56	.006
Emergency	0.3510	1.42	1.13–1.77	.002
Gender, male	0.3855	1.47	1.23–1.75	<.001
Wound class = CO/D	0.4406	1.55	1.20–1.98	<.001
ASA score ≥ 3	0.4772	1.61	1.33–1.95	<.001
Multiple procedures	0.6887	1.99	1.61–2.45	<.001

comparison allows for inclusion of the full range of variables specified in this analysis.

This study has four major limitations. First, the data collected are from an existing surveillance system with a parsimonious set of variables. Potentially important clinical variables, such as underlying diagnosis, use and type of prophylactic antibiotics, or obesity, are not currently available from the NNIS system. Second, infection control professionals in participating NNIS hospitals collected all data for this analysis. Although standard case definitions and methods were used, SSIs may be difficult to define in some patients, and underreporting may occur. However, a previous evaluation study in NNIS hospitals determined that SSI surveillance in ICU patients had 67% sensitivity, 98% specificity, and a positive predictive value of 72%.[19] Third, postdischarge surveillance for SSIs is difficult, and underreporting of SSIs may, in part, explain the differences seen, since patients are generally discharged earlier following laparoscopy.[20] This would be especially true for superficial SSIs. However, in this analysis, both deep incisional SSIs and organ/space SSIs were more frequent following open cholecystectomy, suggesting that the differences seen were not due to underreporting alone. Innovative methods using electronic data have been used to improve postdischarge surveillance and should be considered in prospective studies to evaluate SSI risk.[20,21] Finally, hospitals in the NNIS system may not be representative of all U.S. hospitals: NNIS hospitals are overrepresented by large hospitals, teaching hospitals, and hospitals in the northeastern United States.[22]

As described in this report, the risk of an important adverse health event, SSIs following cholecystectomy, is substantially reduced with the use of minimally invasive technology (laparoscopy). The recent Institute of Medicine report on medical errors highlighted the need for both mandatory and voluntary systems of reporting.[23] Nosocomial infection surveillance was proposed as a potential model for voluntary reporting. Future efforts to develop patient safety monitoring and reporting systems will need to assess the impact of new technology on the incidence of adverse events to appropriately risk-stratify for interfacility or interprovider comparisons. The challenge will be to do this with a parsimonious set of variables that either directly assess risk or are appropriate surrogates.

References

1. Owings MF, Kozak LJ. Ambulatory and inpatient procedures in the United States, 1996. National Center for Health Statistics. Vital Health Stat 13(139), 1998.
2. Horan TC, Culver DH, Gaynes RP, et al. Nosocomial infections in surgical patients in the United States, January 1986–June 1992.
3. Culver DH, Horan TC, Gaynes RP, et al. Surgical wound infection rates by wound class, operative procedure, and patient risk index. *Am J Med.* 1991;91:152S–157S.
4. Emori TG, Culver DH, Horan TC, et al. National Nosocomial Infections Surveillance System (NNIS): description of surveillance methodology. *Am J Infect Control.* 1991;19:19–35.
5. Garner JS, Jarvis WR, Emori TG, et al. CDC definitions for nosocomial infections. *Am J Infect Control.* 1988;85(17):818–27.
6. Horan TC, Gaynes RP, Martone WJ, et al. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC defintions of surgical wound infections. *Infect Control Hosp Epidemiol.* 1992; 13:606–608.
7. Keats AS. The ASA classification of physical status—a recapitulation. *Anesthesiology.* 1978; 49:233–236.
8. Steiner CA, Bass EB, Talamini MA, et al. Surgical rates and operative mortality for open and laparoscopic cholecystectomy in Maryland. *N Engl J Med.* 1994;330:403–408.
9. The Southern Surgeons Club. A prospective analysis of 1518 laparoscopic cholecystectomies. *N Engl J Med.* 1991;324:1073–1078.
10. Watkins DS, Wainwright AM, Thompson MH, et al. Infection after laparoscopic cholecystectomy: are antibiotics really necessary? *Eur J Surg.* 1995;161:509–511.
11. Tocchi A, Lepre L, Costa G, et al. The need for antibiotic prophylaxis in elective laparoscopic cholecystectomy: A prospective randomized study. *Arch Surg.* 2000;135:67–70.
12. Maxwell JG, Tyler BA, Rutledge R, et al. Cholecystectomy in patients aged 80 and older. *Am J Surg.* 1998;176:627–631.
13. Redmond HP, Watson RW, Houghton T, et al. Immune function in patients undergoing open vs laparoscopic cholecystectomy. *Arch Surg.* 1994;129:1240–1246.
14. Vuorisalo S, Haukipuro K, Pokela R, et al. Risk features for surgical-site infections in coronary artery bypass surgery. *Infect Cont Hosp Epidemiol.* 1998;19:229–233.
15. Eachempati SR, Hydro L, Barie PS. Gender-based differences in outcome in patients with sepsis. *Arch Surg.* 1999;134:1342–1347.
16. Kingston RD, Walsh S, Robinson C, et al. Significant risk factors in elective colorectal surgery. *Ann Royal Coll Surg.* 1995; 77:369–371.
17. Centers for Disease Control, Prevention. National Nosocomial Infections Surveillance (NNIS) system report, data summary from January 1990-May 1999. *Am J Infect Control.* 1999;27:520–532.
18. Gaynes RP, Culver DH, Horan TC, et al, the National Nocomial Infections Surveillance System. Surgical site infection (SSI) rates in the United States, 1992–1998: The National Nosocomial Infections Surveillance System Basic SSI Risk Index. *Clin Infect Dis.* 2001; 33(suppl 3):S69–S77.
19. Emori TG, Edwards JR, Culver DH, et al. Accuracy of reporting nosocomial infections in intensive-care unit patients to the National Nosocomial Infections Surveillance system: A pilot study. *Infect Cont Hosp Epidemiol.* 1998;19:308–316.
20. Sartor C, Edwards JR, Gaynes RP, et al. Evolution of hospital participation in the National Nosocomial Infections Surveillance System, 19866 to 1993. *Am J Infect Control.* 1995;23:364–368.
21. Sands K, Vineyard G, Platt R. Surgical site infections occurring after hospital discharge. *J Infect Dis.* 1996;173:963–970.
22. Sands K, Vineyard G, Livingston J, et al. Efficient identification of postdischarge surgical site infections: use of automated pharmacy dispensing information, administrative data and medical record information. *J Infect Dis.* 1999;179:434–441.
23. Institute of Medicine. *To err is human*. Washington DC: National Academy Press, 1999.